

510(k) Summary

Date of Summary: May 4, 2012

Submitted by:

Submitter: Caldera Medical, Inc.
Address: 5171 Clareton Drive
Agoura Hills, CA 91301
Contact: Vicki Gail, Manager QA/RA
Phone: (818) 879-6555 x 102

Device Name:

Device: Surgical Mesh (878.3300)
Trade Name: Vertessa™
Common Name: Surgical Mesh
Classification: Class II, Product Code: OTO - Surgical Mesh, Gynecologic, 21
CFR 878.3300, General And Plastic Surgery
Predicate Device: Ascend® Blue (K101462), Caldera Medical Inc.
POPMesh™ (K053424), Caldera Medical, Inc.

Description of Device:

Vertessa™ is designed to be used in the inpatient or outpatient surgery setting in women suffering from uterine or vaginal vault prolapse and is implanted or affixed using suture of the surgeon's choice. Vertessa™ mesh will be provided sterile and is comprised of macroporous monofilament polypropylene warp knit clear mesh.

Intended Use of Device:

Vertessa™ may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.

Technological Characteristics

Vertessa™ is a modification of the predicate mesh device, Ascend® Blue, which is comprised of the same knit pattern. Vertessa™ has a specific intended use from the predicate device, POPMesh™, and does not change the fundamental scientific technology of the predicate devices.

Performance Summary

In accordance with the FDA's *Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s"* the results of bench, simulated use, surgeon feedback and validation testing has shown Vertessa™ to be substantially equivalent to the predicate devices in its intended use, technological characteristics and performance.

Vertessa™ is comprised of the same mesh as the predicate device, Ascend® Blue, FDA 510(k) #K101462, also a product of Caldera Medical. In accordance with the FDA's *Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh*, the following mesh characteristics were assessed: mesh thickness, mesh knit

characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels. Vertessa™ mesh demonstrates substantial equivalence to the predicate device, Ascend® Blue.

Vertessa™ has passed all biocompatibility testing as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product)*, 3. *Biocompatibility* and *FDA Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing"*. Vertessa™ demonstrates substantial equivalence to the predicate device, Ascend® Blue.

In accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA, FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product)*, 4. *Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, Vertessa™ has passed all testing requirements in terms of aging, shelf life, transportation and sterilization and has demonstrated substantial equivalence to the predicate device, Ascend® Blue.

Results of mechanical bench and validation testing demonstrate equivalent device function based upon its intended use to the predicate devices, POPMesh™ and Ascend® Blue.

The performance of Vertessa™ demonstrates that the device is as safe, and as effective, and performs at least as safely and effectively as the predicate devices, Ascend® Blue and POPMesh™.

Summary of Substantial Equivalence

Vertessa™ is safe and effective for its intended use and is substantially equivalent to the predicate devices, Ascend® Blue and POPmesh™, also products of Caldera Medical.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vicki Gail
Manager, QA/RA
Caldera Medical, Inc.
5171 Clareton Drive
AGOURA HILLS CA 91301

MAY 10 2012

Re: K120327
Trade/Device Name: Vertessa™
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: March 15, 2012
Received: March 15, 2012

Dear Ms. Gail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

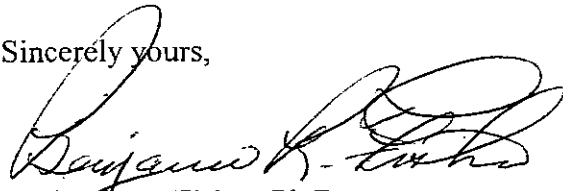
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOoffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over the typed name.

Benjamin R. Fisher, Ph.D.
Director

Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications For Use

Indications For Use

510 (k) Number (if known): K120327

Device Name: Vertessa™

Indications for Use:

Vertessa™ may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.

Prescription Use --X--

AND/OR

Over the Counter Use _____

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Glaine B. Upde for Barry Fisher

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

510(k) Number K120327